

### STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

## WASHINGTON STATE BOARD OF PHARMACY

MEETING MINUTES September 27, 2012

Department of Health Point Plaza East Room 152/153 310 Israel Rd SE Tumwater WA 98501

### **CONVENE**

Chair Christopher Barry called the meeting to order at 9:06 a.m., September 27, 2012

**Board Members:** 

Gary Harris, RPh,

Christopher Barry, RPh, Vice Chair

Elizabeth Jensen, PharmD

Donna Feild, RPh, MBA

Emma Zavala-Suarez, J. D., Public Member

Sepi Soleimanpour, RPh

Dan Rubin, MPP, Public Member

Guest / Presenters:

David Rose, Pharmacy Director for PharMerica

Shawn Moore, Attorney for PharMerica

Bill Fasset, Professor of Pharmacy and Ethics of

of Washington State University

Wendy LaRocque, from the City of Ferndale

Mindy Collins, manages the City of Bellingham

Take Back Program

Rick Johnson, Executive Director of DVM and the

Cowlitz County Humane Society

Staff Member:

Joyce Roper, AAG

Chris Humberson, Executive Director

Grant Chester, Chief Investigator

Stan Moore, Pharmacy Investigator

Tim Fuller, Pharmacist Consultant

Doreen Beebe, Program Manager

Kitty Slater-Einert, Rules Coordinator

Leann George, Program Support

Cathy Williams, Pharmacist Consultant

<u>Introduction: Executive Director – Chris Humberson</u>

Chris Humberson was appointed for the position of Pharmacy Executive Director that took effect September 4, 2012. Chris has over 30 yrs retail pharmacy experience and management experience. In addition he has several years experience in pharmaceutical sales and marketing in both hospitals and

retailing settings. Mr. Humberson is originally from Wyoming. He graduated from the University Of Wyoming School Of Pharmacy in 1982 with a Bachelor of Science degree. He and his wife Kelly currently call Issaquah their home. Chris enjoys history, fine arts and music and sports.

### **CONSENT AGENDA**

Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

- **1.1** Business Meeting Agenda Approval September 27, 2012
- **1.2** Pharmacy & Other Firm Application Approval.
- **1.3** NPLEx Monthly Report Acceptance.
- **1.9** Board Minute Approval.
  - August 16, 2012

Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. **Items 1.4, 1.5, 1.6, 1.7** and **1.8** were **deleted** from the agenda.

**MOTION:** Donna Feild moved that the board approve items 1.1, 1.2, 1.3 and 1.9. Elizabeth Jensen seconded. **MOTION CARRIED: 7-0.** 

#### **REPORTS**

Board Member

Dan Rubin reported:

• He has been using personal knowledge of the philanthropy world to work on finding leads for Prescription Monitoring Program (PMP) funding. He finds it hard to believe that the program won't to be supported long term.

Christopher Barry reported:

- He attended the National Association of Boards of Pharmacy (NABP) Interactive Forum September 19-20, 2012.
  - ✓ There was talk about the future of pharmacy regulation. It seems Washington Board of Pharmacy is ahead as far as pharmacy technician education and continuing education.
  - ✓ There was discussion regarding regulations to decrease diversion and patient safety. PMP plays a big role in this and was major part of this discussion.
  - ✓ Drug shortages, some states are looking at ways to extend the out date of some products and how to use single does vials more effectively. A big piece of this discussion was secondary versus gray market pharmacies and pharmacies selling to the gray market.
  - ✓ Christopher Barry did notice that there is almost no one from the west coast on the NABP he believes the west coast should be more represented.

Executive Director *Chris Humberson reported:* 

- Chris has been working on the rules re write to help and support Kitty Slater and has made contact with Idaho Board of Pharmacy to get some input on their process of re writing the rules.
- Getting up to speed on credentialing
- He has reached out to Oregon and Idaho bop to contact their Executive Director's
- Chris is learning where program is regarding projects
- He will be attending the NABP Annual District Meeting in Little Rock, Arkansas.

### **Assistant Attorney General**

Joyce Roper reported:

• There is a case involving the North Carolina Dental Board and the FTC, which might have some implications for regulating unlicensed practice of professions. The AG's office has been monitoring it and advising the other boards and commissions presently considering some activity that could be implicated by the federal court decision in the North Carolina case. Fortunately, this board's current priorities and activities are not implicated by that case. We will continue to monitor the North Carolina case and advise the boards and commissions if their activities may be affected by that case.

#### **Consultant Pharmacists**

*Tim Fuller reported:* 

• A To-Quyen an extern from Washington University will be coming next week.

# Chief Investigator

Grant Chester reported:

- There continues to be some confusion in pharmacies since the Drug Enforcement Administration (DEA) published their new regulation allowing multiple prescriptions for schedule II controlled substances in 2007. (21CFR1306.12(a)) In summary an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90 day supply of a schedule II controlled substance providing the following conditions are met:
  - ✓ <u>Each separate prescription\*</u> is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
  - ✓ The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
  - ✓ The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
  - ✓ The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
  - ✓ The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.
  - ✓ To clarify <u>each separate prescription</u> must be on a separate prescription blank.
  - ✓ While not encouraged by the DEA multiple controlled substance prescriptions may be written on the same prescription blank only if they are all to be filled at the same time. The most common example is a discharge prescription from a hospital.

### **DISCUSSIONS**

### EZ Mar – Electronic Prescription Transmission System

The board reviewed the proposal by PharMerica for approval of the EZ Mar system for the electronic communication of prescription information from the long-term care facility to the pharmacy. Note, the board's approval was reconsidered at the April meeting and postponed further discussion / decision for a future meeting.

# **Background:**

- A pharmacist investigator inspected the PharMerica pharmacy and found they were using an unapproved electronic prescription system initially called Paperless and now called EZ MAR. Inspection of the applications found nurses performing order entry and the pharmacy did not receive a copy of the original order. This was the case in a small hospital and in two nursing homes. The small hospital operation was in violation of WAC 246-873-080(5) which requires that the pharmacist to review a direct copy of the order.
- The EZ MAR system is now based upon nurse order entry in one nursing home. The pharmacy receives the electronic prescription, prints it and re-enters in to the AS400 pharmacy computer system. Procedures call for monthly Physician Order Entry sheets to be signed by the nurse and then by the pharmacists. This was not done consistently. Neither prescribers nor pharmacists enter medication orders into EZ MAR.
- We determined that the EZ MAR system is a Medication Administration system and PharMerica representatives agreed. Without the direct involvement of the prescriber or the pharmacist, the EZ MAR system does not meet the definition of a system for transmitting electronically communicated prescription information as defined in RCW69.41.055. It facilitates the nurses with medication administration.
- PharMerica says they have adequate auditing processes to determine diversion and that the pharmacist checks with the prescriber on all controlled substance prescriptions and some legend drug prescriptions as well. The prescriber and the pharmacist consultant only review orders every 30 days. PharMerica has been asked to provide the board with some statistics on the pharmacist verification of legend drug prescriptions.asy to divert medications with EZ MAR for a considerable length of time since.

This has been recognized that it is not an electronic prescription transmission system. The board will not need to take action at this point.

### Automated Drug Distribution Device Approval Revisited.

Tim Fuller led the discussion to the board asking them to evaluate each program's compliance with rule (Chapter 246-872 WAC). These are revised policies and procedures for the use of automated drug distribution devices discussed at the August meeting.

a) Franciscan Hospice and Palliative Care

**MOTION:** Gary Harris moved that the board approve the revised policy and procedure stating that a patient will be removed from the system within 12 hours of being discharged or deceased. Elizabeth Jensen second. **MOTION CARRIED: 7-0.** 

b) Skagit Valley Hospital: Mt Vernon and Arlington

**MOTION:** Gary Harris moved that the board will approve the ADDD if a change is made to the policy and procedures to state "pharmacy personnel *shall* do the stocking". Elizabeth Jensen seconded. Dan Rubin abstained. **MOTION CARRIED: 6-1.** 

c) Walla Walla General Hospital

**MOTION:** Donna Feild moved that the board approve this ADDD if they add a piece to the policy and procedure. The board requires them to add a list of comprised medications that a delay in administration can potentially cause harm to a patient. Elizabeth Jensen seconded. **MOTION CARRIED: 7-0.** 

d) Mason General Hospital

**MOTION:** Elizabeth Jensen moved to approve Mason General Hospital's ADDD. Donna Feild seconded. **MOTION CARRIED: 7-0.** 

### **Euthanasia Training Program**

The board was asked to consider a request from Ann Langer, DVM and the Cowlitz County Humane Society for approval of its euthanasia training program.

#### **Course Outline:**

- Training shall consist of two parts; lecture and practical training.
- It will be taught by a licensed and experienced veterinarian, Ann Langer, DVM.
- There will be a minimum of 2 two hour lectures with demonstration and hands on practice of techniques. If the materials cannot be covered sufficiently in the allotted four hours, additional time will be scheduled.
- Trainees will be required to have read "The Humane Society of the United States Euthanasia Training Manual" by Rebecca H. Rhoads, DVM and the American Humane Association "Euthanasia by Injection Training Guild" prior to the lecture series. These manuals shall be the basis for the training.
- The details in these references shall be the basis for the training lecture and the details within these manuals and their pictures will be referred to directly during the lecture. Reference pages are noted on the outline.
- After completion of the training program, the student must pass a written test with a passing score of 75% or greater and pass a practical test consisting of euthanasia of a dog and a cat. The student will explain the complete process step-by-step while performing the procedure.
- Verbalized questions will focus on safety issues and what will be done if something goes wrong. After training is completed, a certificate will be awarded: "Certificate of Successful Completion of Washington State Board of Pharmacy Approved Euthanasia Training Course".

**MOTION:** Elizabeth Jensen moved that the board approve the DVM and the Cowlitz County Humane Society euthanasia training program. Gary Harris seconded. **MOTION CARRIED: 7-0.** 

## City of Ferndale Household Pharmaceutical Waste Take-Back Program Revisited

The board was asked to consider for approval the City of Ferndale pharmaceutical take-back program. The requestor, Wendy LaRocque was supported by Mindy Collins who presented the City of Bellingham's take-back program to the board recently. They came to the answer questions, particular those that concern the security of the take back receptacle. It seems the receptacle is opened more times than necessary. This item was carried forward from the August meeting.

Wendy was influenced by the board approved pilot program for return of pharmaceuticals and proper disposal. The safe removal of waste pharmaceutics is important in Ferndale to protect the environment, reduce childhood poisonings and adverse effects, and reduce diversion and abuse of pharmaceuticals. **Overview:** 

- Any and all unwanted pharmaceuticals from households could be taken back to any pharmacy. For over-the-counter medications, prescription drugs, free samples, or dietary supplements (vitamins). This would not include DEA controlled substances,
- Pharmacists could accept pharmaceuticals during open hours via a mail-box-style slot or a secured locking container near the pharmacy counter. Pharmacists would not handle or inventory the type of pharmaceuticals being returned. Pharmaceuticals would be collected in their packaging, and customers would be given an opportunity to remove or mark-out all identifying information.
- The waste pharmaceuticals would fall into a collection bucket, which could be serviced by the same distributor who delivered pharmaceutical products to the pharmacy. Each secured bucket would have tracking technology to identify and track the shipment of the material. The distributor would consolidate waste household pharmaceuticals from all their serviced pharmacy locations. The distributor would subsequently arrange for final disposal following procedures approved by the Washington State Board of Pharmacy and the Washington State Department of Ecology.
- Final disposal would occur at an incinerator meeting specifications for time and temperature requirements, and would follow air quality emission standards, irretrievable destruction, and safety requirements.

**MOTION:** Dan Rubin moved that the board approve the request by the City of Ferndale's Pharmaceutical Take-Back Program. Donna Feild seconded. **MOTION CARRIED: 7-0.** 

### Authorizing the Use of Non-Child Resistant Containers

Grant Chester led the discussion asking the board to consider approving the use of electronic technology to capture the authorizing signature of the patient or his/her agent requesting that container used is not child-resistant (WAC 246-869-230). Grant provided the board with some brief background and the issues that have been coming up.

The Board of Pharmacy (BOP) has interpreted WAC 246-869-230 to allow both manual and electronic signatures. The statement required for NCRC can be as short as yes or no in response to a question whether NCRC's are requested. The request and waiver can be part of a series of question asked at the same time. Since the rule is silent on the frequency with which signatures must be renewed the BOP did not address this issue. The electronic signatures kept as part of an automated medication record system must be retrievable within 72 hours in accordance with WAC 246-875-060. The board recommended that staff put this interpretation into the next newsletter.

Implementation of Pharmacy Value Stream Mapping (VSM) Event Process Improvements

The board received an update on the implementation of authorized changes following the Pharmacy VSM Event and close out report. Additional application changes for consideration include removing the requirement for an applicant's photo, and determining documents necessary to show an applicant is eligible for exams.

**MOTION:** Donna Field moved that the board remove the requirement for an applicant to provide a photo. Elizabeth Jensen seconded. **MOTION CARRIED: 7-0.** 

**MOTION:** Elizabeth Jensen moved that the board remove the requirement that Intern hours be sent to the board to show that an applicant is eligible for exams. Donna Feild seconded. **MOTION CARRIED: 7-0.** 

### Delegation of Authority

Joyce Roper led the discussion with the board regarding the delegation of authority to department/program staff. Joyce did some research to see if it is appropriate for department/staff to be delegated authority for approval of some practices.

List of items not appropriate for final approval by department/staff:

- Electronic prescription transmission systems
- Ancillary utilization plans
- Continuing Education
- Tamper Resistant Prescription Pads
- Renewal of Technician Training Programs

These items can be prepared for the boards review and put in the Consent Agenda Items for the boards review and approval.

The board adjourned for Executive Session and Case Presentations at 12:00 p.m.

The board reconvened from Executive Session and Case Presentations at 1:04 p.m.

### **PRESENTATIONS**

### Rules Update

The board will hear an update on proposed rulemaking workload and agency request legislation.

- Animal Control Rule is pending file through the Code Revisers.
- Pharmacy Technician Training requirement for Continuing Education has been filed and working on sending out letters to Pharmacists and Pharmacy Technicians.
- Pharmacy Practice Experiences & Internships still waiting for an exemption.

### Prescription Drug Shortages

Tim Fuller provided some information on the growing concerns regarding drug shortages. Stan Moore shared some things the investigators see out on the field.

### Correspondence

The board discussed correspondence received or distributed.

- a) Ther-Rx Corp. letter re: Compounding of Hydroxyprogesterone Caproate
- b) ISMP Medication Safety Alert September 6, 2012

### National Association of State Controlled Substances Authority Annual Meeting

The board will discuss the NASCSA 2012 Resolutions and consider naming Steve Saxe voting delegate for the board.

#### **Resolutions:**

1. A RESOLUTION RECOMMENDING DETAILED REPORTING BY LAW ENFORCEMENT OF CRIMINAL OFFENSES INVOLVING CONTROLLED SUBSTANCE.

**MOTION:** Dan Rubin the board does not support this resolution as written. The board recommends more support for the Prescription Monitoring Program versus placing unfunded additional reporting burdens on state and local criminal justice. Elizabeth Jensen seconded. **MOTION CARRIED: 7-0.** 

2. A RESOLUTION RECOMMENDING STATES EVALUATE AND IMPROVE STATUTES AND REGULATIONS ENABLING THEM TO ELIMINATE ILLEGITIMATE MEDICAL CLINICS COMMONLY KNOWN AS "PILL MILLS."

**MOTION:** Elizabeth Jensen the board has concerns and will abstain from making a motion until the board can have some collaboration with Nursing and Medical. There is no information provided to make a recommendation. Sepi Soleimanpour seconded. **MOTION CARRIED:** 7-0.

3. A RESOLUTION SUPPORTING EFFORTS TO SAFEGUARD THE U.S. DRUG SUPPLY CHAIN FROM SUBSTANDARD, INEFFECTIVE, AND COUNTERFEIT DRUGS.



**MOTION:** Elizabeth Jensen moved that the board support this resolution. The board would like to be provided more background in the future. Donna Feild seconded. **MOTION CARRIED:** 7-0.

**MOTION:** Elizabeth Jensen moved that the board name Steve Saxe as the voting delegate for the Washington State Board of Pharmacy at the National Association of State Controlled Substances Authority Annual Meeting. Donna Feild seconded. **MOTION CARRIED: 7-0.** 

### **OPEN FORUM**

Jeff Rochon with Washington State Pharmacy Association (WSPA)

- Jeff welcomed Chris Humberson
- Washington State Hospital Association is working with WSPA on a Partnership for Patients effort which is focused on two topics: anticoagulation and opioid abuse.
- WSPA has been receiving a number of calls this week on the DEA's interpretation of pharmacists sending refill requests for controlled substances. Since the DEA is saying that the pharmacist is usually not an "agent of the prescriber", these refill authorization forms can no longer be used. A prescriber or an agent of the prescriber must prepare the prescription and the prescriber must sign it. WSPA has been told that a pharmacy can send a refill request for C3-5 but a prescriber must rewrite the prescription.
- He thanked Chris Humberson for attending the Labor and Industries Hazardous Drugs Advisory Committee meeting. This Committee will be meeting monthly to guide implementation of the new rule.

#### PRESENTATION OF AGREED ORDERS

#### **CASE PRESENTATION**

Respectfully Submitted by:	
Leann George, Program Suppo	



# Approved on November 8, 2012

Christopher Barry, Chair Washington State Board of Pharmacy

